



[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 141 0141]

Novartis AG; Analysis of Proposed Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before March 25, 2015.

ADDRESSES: Interested parties may file a comment at

<https://ftcpublic.commentworks.com/ftc/novartisgskconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Novartis AG GlaxoSmithKline - Consent Agreement; File No. 1410141” on your comment and file your comment online at

<https://ftcpublic.commentworks.com/ftc/novartisgskconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “Novartis AG GlaxoSmithKline - Consent Agreement; File No. 1410141” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D),

Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Stephanie Bovee, Bureau of Competition, (202-326-2083), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for February 23, 2015), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 25, 2015. Write “Novartis AG GlaxoSmithKline - Consent Agreement; File No. 1410141” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card

number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which . . . is privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/novartisgskconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you file your comment on paper, write “Novartis AG GlaxoSmithKline - Consent Agreement; File No. 1410141” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 25, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Novartis AG ("Novartis"), which is designed to remedy the anticompetitive effects of Novartis' proposed acquisition of oncology assets from GlaxoSmithKline PLC ("GSK"). The Commission has placed the proposed Consent Agreement on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with any comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to an agreement dated April 22, 2014 (the "Agreement"), Novartis proposes to acquire GSK's marketed oncology products and two pipeline oncology compounds for approximately \$16 billion (the "Transaction"). GSK currently has a BRAF inhibitor and an

MEK inhibitor approved by the FDA, as well as the only BRAF/MEK combination therapy approved for sale in the United States. BRAF and MEK inhibitors are medicines that inhibit molecules associated with the development of cancer. Novartis has BRAF and MEK inhibitors in late-stage development, as well as a BRAF/MEK combination therapy that it expects to launch in the near future.

The Commission alleges in its Complaint that the Transaction, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in U.S. markets for BRAF inhibitors and MEK inhibitors. The proposed Consent Agreement will remedy the alleged violations by preserving competition that the Transaction would otherwise eliminate. Under the terms of the Consent Agreement, Novartis is required to divest all rights and assets related to LGX818, its BRAF inhibitor, and MEK162, its MEK inhibitor, to Array BioPharma Inc. (“Array”).

II. The Relevant Products and Markets

The relevant markets in which to analyze the Transaction are the development and sale of BRAF inhibitors and MEK inhibitors. BRAF and MEK inhibitors are orally administered, targeted oncology products. Physicians currently use BRAF and MEK inhibitors, increasingly in combination, to treat metastatic, late-stage melanoma. Last year in the United States, there were approximately 76,100 new cases of melanoma and 9,710 deaths caused by melanoma.² In addition to melanoma, researchers are studying BRAF and MEK inhibitors as potential treatments for a range of cancers, including ovarian cancer, colorectal cancer, and non-small cell lung cancer.

² U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, “Melanoma,” <http://www.cancer.gov/cancertopics/types/melanoma>.

The United States is the relevant geographic market in which to assess the competitive effects of the Transaction because the FDA must approve BRAF and MEK inhibitors, as well as the use of the two inhibitors in combination, for marketing and sale in the United States. Accordingly, products sold outside of the United States, but not approved by the FDA, are not alternatives for U.S. consumers.

The BRAF and MEK inhibitor markets in the United States are highly concentrated. Tafenlar®, sold by GSK, and Zelboraf®, sold by F. Hoffman-La Roche AG (“Roche”), are currently the only FDA-approved BRAF inhibitors. Novartis’ BRAF inhibitor in development, LGX818, is the only other product likely to begin competing with GSK and Roche in the near future. GSK’s Mekinist® is currently the only FDA-approved MEK inhibitor, while Novartis’ MEK162 is one of only a small number of MEK inhibitors in late-stage clinical development. GSK also sells the only FDA-approved BRAF/MEK combination therapy, which is comprised of Tafenlar and Mekinist. Aside from GSK, Roche and Novartis are the only companies with BRAF/MEK combinations in late-stage development.

III. Entry

Entry into U.S. markets for BRAF inhibitors and MEK inhibitors would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Transaction. Like other oncology products, BRAF and MEK inhibitors must complete clinical trials and garner approval by the FDA before they can enter the U.S. markets. Development of new oncology medicines is expensive, time consuming, and has a high rate of failure. The time and resources required to develop and market a new oncology medicine make it unlikely that *de novo* entry into the relevant markets would be sufficient to offset the anticompetitive effects of the Transaction, and no firms currently have products in development that are likely to enter and prevent competitive harm from the Transaction.

IV. Effects of the Acquisition

Without a remedy, the Transaction will eliminate likely future competition between GSK and Novartis in the concentrated markets for BRAF and MEK inhibitors. Absent the acquisition, Novartis likely would have obtained FDA approval for and launched its LGX818 and MEK162 products in the near future in direct competition with GSK's combination offering for treating metastatic melanoma patients. The Transaction would also likely reduce the development of BRAF and MEK inhibitors to treat other types of cancer, because GSK and Novartis are currently developing their respective BRAF and MEK inhibitors for several of the same indications beyond melanoma. By eliminating the potential head-to-head competition between Novartis and GSK, the Transaction will likely result in higher prices for BRAF and MEK inhibitors and reduced choice for U.S. health care consumers.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Transaction's anticompetitive effects by requiring Novartis to divest to Array all of its rights and assets related to LGX818 and MEK162. The divestiture will preserve the competition that otherwise would have been lost in the markets for BRAF and MEK inhibitors.

Array is a biopharmaceutical company headquartered in Boulder, Colorado, that focuses on the discovery, development, and commercialization of oncology medicines. Array is well suited to acquire LGX818 and MEK162 because it initially developed MEK162 and is currently a partner with Novartis in the development of both products. Array is a sophisticated company that possesses both the incentive and ability to develop and commercialize LGX818 and MEK162 either independently or with a new partner.

The Order requires Novartis to divest its rights and interests in LGX818 and MEK162 to Array no later than ten days after consummation of the proposed transaction or on the date that

the Order becomes final, whichever is earlier. The divestiture includes regulatory approvals, intellectual property, assets related to ongoing clinical trials and manufacturing processes, and other confidential business information related to the divested compounds. To ensure that the divestiture is successful, the Order requires Novartis to provide transitional support to Array and to manufacture and supply the divested compounds while it transfers manufacturing processes to Array.

The Commission has agreed to appoint an Interim Monitor to ensure that Novartis complies with all of its obligations under the Consent Agreement and to keep the Commission informed about the status of the transfer of rights and assets to Array.

The Commission's goal in evaluating possible divestiture purchasers is to maintain the competitive environment that existed prior to the Transaction. If the Commission ultimately determines that Array is not an acceptable acquirer, or that the manner of the divestiture is unacceptable, then the parties must unwind the sale of rights and assets to Array and divest them to a Commission-approved acquirer within six months of the date that the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the rights and assets if the parties fail to divest them as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement; it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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